DePuy ACE™

OCT 26 1998

K983265

510(k) SUMMARY

NAME OF FIRM:	DePuy ACE Medical Company 2260 East El Segundo Boulevard El Segundo, CA 90245
510(k) CONTACT PERSON:	Kathleen Dragovich Regulatory Affairs Specialist DePuy ACE Medical Company
TRADE NAME:	DePuy ACE Composite Locking Nut
COMMON NAME:	Nut, Orthopedic
CLASSIFICATION:	888.3030 Single/multiple component metallic Bone fixation appliances and accessories. Class II
DEVICE CODE:	87HTN
SUBSTANTIALLY EQUIVALENT DEVICES:	DePuy ACE Nut for Cortical Bone Screw DePuy ACE Washer

INTENDED USE:

The DePuy ACE Composite Locking Nut is used as follows:

Cortical bone screws (alone)
Intramedullary nails as locking bolts
Screws with plates
Where extra purchase in far cortex is required

DEVICE DESCRIPTION AND SUBSTANTIAL EQUIVALENCE RATIONALES:

The device is a nut with a 10mm hex. This nut is made from a composite of a UHMW Polyethylene nut with a built-in Titanium washer. The washer will aid in fixation in osteoporotic bone by helping to distribute the load against the bone.

The DePuy ACE Composite Locking Nut is a combination of the DePuy ACE Nut for Cortical Bone Screws which received clearance under 510(k) K874669 and the DePuy ACE Washer which received clearance under 510(k) K895107. The function of the DePuy ACE Composite Locking Nut is a combination of both the nut and the washer: to act as the mating part to a screw for better fixation and to increase the surface under the nut to help distribute the load against the surface of the bone.

Testing has shown that the ultimate torque is approximately 10 times that of the insertion torque; therefore, the nut can be applied without rounding the nut. This distinct difference indicates that upon insertion and advancement of the nut, the surgeon will be able to clearly identify that the nut is seated against the bone prior to accidental over-torque of the nut. (See Test Report ET 63-001 in Exhibit IV.)

Based on the above information, DePuy ACE believes that the DePuy ACE Composite Locking Nut is substantially equivalent to the DePuy ACE Nut for Cortical Bone Screw and the DePuy ACE Washer.

0

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 1998

Mr. Paul Doner
Director, Regulatory and Clinical Affairs
DePuy ACE Medical Company
2260 East El Segundo Boulevard
El Segundo, California 90245

Re: K983265
Trade Name: DePuy ACE Composite Locking Nut
Regulatory Class: II
Product Code: HTN
Dated: September 15, 1998
Received: September 17, 1998

Dear Mr. Doner:

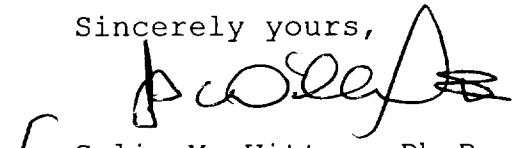
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DePuy ACE

510(k) Number (if known) _____

Device Name: **DePuy ACE Composite Locking Nut**

Indication for Use:

The DePuy ACE Composite Locking Nut is used as follows:

Cortical bone screws (alone)
Intramedullary nails as locking bolts
Screws with plates
Where extra purchase in far cortex is required

_____

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X **OR** Over-The-Counter _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983265